

# Social Sciences/Behavioral Adult Informed Consent

North Dakota Department of Human Services  
Information for People Who Take Part in Research Studies

---

The following information is being presented to help you decide whether or not you want to be a part of a minimal risk research study. Please read carefully. If you do not understand something, ask the Person in Charge of the Study.

**Title of Study:** \_\_\_\_\_

**Principal Investigator:** \_\_\_\_\_

**Study Location(s):** \_\_\_\_\_

You are being asked to participate because... *(Indicate why the subject is being asked to participate. Try to keep the language clear & simple.)*

## General Information about the Research Study

The purpose of this research study is to...*(Explain completely)*

## Plan of Study

- *(Explain in detail what the subject will be required to do and how much time will be needed (e.g. weeks, days, hours, etc.)*
- **Payment for Participation**  
*[If the subjects are to be paid or compensated, specify the dollar amount and address the consequences of subject withdrawal or termination by the investigator; otherwise, simply state- You will not be paid for your participation in this study].*

## Benefits of Being a Part of this Research Study

- *(Explain what the benefits are, if any, to the subjects. For example, "You will experience..." or, "By taking part in this research study, you may increase our overall knowledge of your..." ) Again, this explanation should be simple & clear.*

## Risks of Being a Part of this Research Study

- *(Explain what the risks are, even if they are minimal. Also, if there are no risks, so indicate.)*

## Confidentiality of Your Records

- Your research records will be kept *(Describe how)* to protect your privacy to the full extent of the law. However, authorized research investigators, the Department of Health and Human Services, the North Dakota Department of Human Services' Institutional Review Board, and other entities/individuals as required or authorized by law, may inspect your records from this research project.
- The results of this study may be published. However, the data obtained from you will be combined with data from other people in the publication. The published results will not include your name or any other information that would in any way personally identify you.  
*[Be sure to explain whether code names or numbers will be used, who will have access to the data, and where will the data be kept.]*

## Volunteering to Be Part of this Research Study

- Your decision to participate in this research study is completely voluntary. You are free to participate in this

research study or to withdraw at any time. If you choose not to participate, or if you withdraw, there will be no penalty or loss of benefits that you are entitled to receive. ***(You may wish to be explicit- e.g., removal from treatment, no grade penalty).***

### Questions and Contacts

- If you have any questions about this research study, contact ***(Identify person(s) and their telephone numbers.)***
- If you have questions about your rights as a person who is taking part in a research study, you may contact Dr. Christine Kuchler, Chair of the Department of Human Services' Institutional Review Board at 1-888-328-2662. ***[Required]***

### Your Consent—By signing this form I agree that:

- I have fully read or have had read and explained to me this informed consent form describing a research project.
- I have had the opportunity to question one of the persons in charge of this research and have received satisfactory answers.
- I understand that I am being asked to participate in research. I understand the risks and benefits, and I freely give my consent to participate in the research project outlined in this form, under the conditions indicated in it.
- I have been given a signed copy of this informed consent form, which is mine to keep.

\_\_\_\_\_  
Signature of Participant  
***[Required]***

\_\_\_\_\_  
Printed Name of Participant

\_\_\_\_\_  
Date

### Investigator Statement

I have carefully explained to the subject the nature of the above protocol. I hereby certify that to the best of my knowledge the subject signing this consent form understands the nature, demands, risks and benefits involved in participating in this study.

\_\_\_\_\_  
Signature of Investigator  
Or Authorized research investigators  
designated by the Principal Investigator  
***[Required]***

\_\_\_\_\_  
Printed Name of Investigator

\_\_\_\_\_  
Date

## Institutional Approval of Study and Informed Consent

This research project/study and informed consent form were reviewed and approved by the North Dakota Department of Human Services' Institutional Review Board for the protection of human subjects. This approval is valid until the date provided below. The board may be contacted at 1-888-328-2662.

**Consent Form Approval Date:**

**Approved Consent Form Expiration Date: *(Your proposed expiration date is subject to IRB review.)***

- If this informed consent form has an "approval expiration date" that expires before the completion of this research study, the Principal Investigator may contact you for your re-consent at the time of expiration.

**Optional: (Please note: the statements below are optional, and may not apply to your study. Please delete them from this consent form if they do not apply.)**

*(This statement needs to be included if you are mailing the consent forms to the subjects and you will not be present when the subject signs this form.)*

Investigator Statement:

I certify that participants have been provided with an informed consent form that has been approved by the North Dakota Department of Human Services' Institutional Review Board. That contains the nature, demands, risks and benefits involved in participating in this study. I further certify that a phone number has been provided in the event of additional questions.

\_\_\_\_\_  
Signature of Investigator

\_\_\_\_\_  
Printed Name of Investigator

\_\_\_\_\_  
Date

### In Case of Illness or Injury

- Call *(list your name and phone number here)* in the event you get sick or injured while participating in this study. If you have an emergency, go to the closest emergency room or clinic for treatment.
- After you have been treated for your illness or injury, call the North Dakota Department of Human Services' Risk Manager at 701-328-2311, who will investigate the matter.

**If you are including Non-English speaking subjects in your study, a consent form in their language is required.**